

REMARKS

Claims 34 to 38 remain in the application and stand rejected. Claim 34 is amended to overcome the rejection thereof under Section 112, second paragraph.

Claims 34 and 35 stand rejected under 35 USC §102(e) as being anticipated by Bierman et al (U.S. Patent No. 6,663,600). Claims 34 to 37 stand rejected under 35 USC 103(a) as being unpatentable over Ash et al (U.S. Patent No. 5,947,953) in view of Bierman et al or Raulerson (U.S. Patent No. 4,037,599). Claim 38 stands rejected under 35 USC §103(a) as being unpatentable over Ash et al in view of Bierman et al or Raulerson and further in view of Cazal (U.S. Patent No. 5,800,414). Claims 34 to 38 also stand rejected under “nonstatutory obviousness-type double patenting” in view of Serial No. 10/974,267.

In the presently claimed invention, the hub member is easily securable to the catheters by snap fit around continuing lengths of the proximal portions of the catheter so that the proximal catheter ends extend beyond the hub for attachment to fittings and, preferably, extension tubes. More importantly, the hub's site is optimally selectable by the practitioner after catheter implantation and subcutaneous tunneling of the catheter proximal end portions, who may have to trim the length of the catheter tubes rather than rely on an immediately available extensive inventory of catheter lengths needed to address needs of different patients. Further, the hub member is releasable from the catheter should it become necessary to repair the catheter: the present invention also provides for repair of catheters that have already been implanted into a patient, without removing a damaged catheter from the patient and re-implanting a new one, causing accompanying distress and risk to the patient. Reference is made to the Specification at paragraphs [0006] to [0008] and [0057] and [0059]. Thus, the presently claimed invention is a greatly advantageous breakthrough in catheter implantation and repair procedures.

References Bierman et al, Ash et al and Cazal have been discussed and distinguished in previous responses.

The Office Action asserts by way of the drawing on page 3, that first and second catheters project proximally from the retainer and the hub 112. There is no reasonable basis for this assertion. The identified branches 114,116 are not portions of the catheter 8,118 but instead are the equivalent of the extension tube assemblies of the present application, and which having fittings or connectors on both ends as indicated by the dashed lines at the retainer, and which extend distally into the retainer and to the hub 112. Reference is made to Bierman et al at column

3, lines 17 to 32, wherein it is stated: “The catheter is one which includes a single elongated body extending proximally from one side of the branching site and at least two elongated bodies extending distally from the other side of the branching site, thereby forming a “Y” shaped junction, or “Y-site”.” (Since Bierman et al considers the proximal direction to be that direction extending to the incision in the patient, and the distal direction to be that direction extending to the connections with extracorporeal medical devices at 114,116, the terms “proximal” and “distal” are reversed from the definition provided in the present application.) Therefore, Applicants respectfully traverse the assertion.

Claim 34 includes the limitation that the extension tube assemblies are connectable to ends of the proximal end portions of the catheters that extend beyond the hub member of the claim. Reference Bierman et al fails to meet this limitation since its catheter 8,118 ends at hub 112 and its extension tube assemblies/branches 114,116 begin at hub 112, and thus fails to anticipate. Applicants respectfully traverse the rejection.

The Office Action characterizes reference Ash et al as having a “hub member 24 adapted to be releasable attachable to and round the first and second proximal end regions of the first and second catheters distally of the proximal ends thereof”. However, this assertion is not correct, since the catheter ends conclude within the hub 24 and do not project proximally thereof; the distal ends of the two extension tubes also conclude within the hub 24 to establish fluid communication with the respective catheters within the hub; later, the Office Action states that the hub 24 is not disclosed to be releasably attachable around the proximal end regions. Reference is made to Figure 2 of Ash et al, wherein it is clearly shown that the catheters 26, 30 end at 62,66 inside the hub 24, and the extension tubes 84,90 begin at 86,92 inside the hub 24. Applicants respectfully traverse the characterization of reference Ash et al by the Office Action.

Reference Raulerson sets forth a catheter assembly including a coaxial dual-lumen catheter, extension tube assemblies, and a hub member for joining the catheter to the extension tube assemblies to establish fluid communication between each extension tube assembly 40,42 and a respective one of the inner and outer lumens of the catheter. Figure 2 clearly shows that the outer lumen of the catheter concludes at seal 64 in recess 59, and the inner lumen ends at seal 62 in recess 57, with channels 25,27 defined in the hub member extending proximally therefrom to the proximal end 38 of the hub member whereat are affixed distal ends of extension tubes 44,46 with fittings affixed thereon. The hub member of Raulerson is hinged to be attached to an end of a

coaxial catheter to join the catheter lumens to respective extension tubes thereof, and is not movable along the catheter from one position to another. Reference is made to column 3, lines 2 to 6, wherein it is stated that the outer tube element terminates a spaced distance from the end or extremity of the inner tube. The position of the hub is not selectable along the length of the catheter but must be placed at the end of the catheter. Thus, the assertion in the Office Action that the hub is “releasably attachable to and around the first and the second proximal end regions **distally of the proximal end**” is respectfully traversed.

In the discussion in the Office action at the top of page 5, the grounds of rejection of claim 34 focus on the hub member being releasably attachable to [something]. However, the Office Action fails to consider the claim as a whole, including the positive limitation that the catheter proximal end regions extend completely through and beyond the hub, where they are then connected to extension tubes at a location proximal of the hub. When each reference is properly considered as a whole, the combination of references fails to meet this limitation. Applicants respectfully traverse the rejection.

Claims 35 to 37 depend from claim 34, which is believed to patentably distinguish over the reference, and therefore, claims 35 to 37 are believed patentable.

With respect to the rejection of claim 38 over Ash et al in view of Raulerson or Bierman et al and Cazal, Cazal does not teach adhesive to be splittable but instead expressly teaches that a drop of adhesive be placed at the end of already split proximal ends to prevent further splitting. Applicants continue to traverse the rejection. Additionally, claim 38 depends from claim 34, which is believed to be patentable.

Claims 34 to 38 stand rejected for “nonstatutory obviousness-type double patenting” in view of the claims of pending but later-filed continuation-in-part application Serial No. 10/974,267. The present rejection is only provisional, since the present application has a filing date earlier than the other application and once all other rejections of the present claims is overcome, the double patenting is required to be withdrawn and the present application issue.

The claims are believed to distinguish patentably over the prior art, and allowance thereof is respectfully urged. No new limitations have been entered into the claims, and no new issues are raised. No new matter has been entered hereby. If any additional fees are due, please charge same to Deposit Account No. 50-2434.

Respectfully Submitted,

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Date

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